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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,387	12/12/2003	Marie-Madeleine Cals-Grierson	016800-655	8526

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EXAMINER	
HENLEY III, RAYMOND J	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,387	CALS-GRIERSON, MARIE-MADELEINE	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-23 ARE PRESENTED FOR EXAMINATION

Election/Restrictions

Initially, an informality is noted at page 1, paragraph [0002] of the present specification, i.e., "[0002] Copending application Serial No. _____ (Attorney Docket No. 016800-654), filed concurrently herewith and assigned to the assignee hereof.". Also, it is noted in the Oath/Declaration that priority under 35 U.S.C. § 371 is claimed based on PCT/FR02/02064, filed June 14, 2002 and under 35 U.S.C.§ 119 (a-d).

In response to this Office action, it would be appreciated if Applicants could provide the missing Application Serial No. Also, it would benefit Applicants, and would appreciated by the Examiner, if an English Language translation could be provided of either document, i.e., to confirm that the present application is a continuation of the PCT/priority document and to gain the benefit of the filing date of such documents, i.e., because the documents are not in English, such documents cannot be used for the purpose of antedating a reference that the Examiner might discover during the examination process of the present application.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 2 and 3, drawn to methods, i.e., a regime or regimen, for slowing or inhibiting cell differentiation and/or proliferation **or** for slowing or inhibiting the growth of epidermis and/or treating hyperproliferative disorders, both comprising the administration of an

effective amount of N,N'-bis(2-pyridyl)methyl-N-N'-bis(3,4,5-trimethoxybenzyl) ehtylenediamine;

Group II, claims 4 and 5, drawn to a method, i.e., a regime or regimen, inhibiting the degradation and/or destruction or cells **or** inhibiting a cellular apoptotic process, both comprising the administration of an effective amount of N,N'-bis(2-pyridyl)methyl-N-N'-bis(3,4,5-trimethoxybenzyl) ehtylenediamine;

Group III, claim 6, drawn to a method, i.e., a regime or regimen, for treating intrinsic and/or extrinsic aging, comprising administering to an individual in need of such treatment, an effective NO-synthase inhibiting amount of N,N-bis(2-pyridyl)methyl-N,N-bis (3,4,5-trimethoxybenzylethylenedinmine;

Group IV, claim 7, drawn to a method, i.e., a regime or regimen, for inhibiting or suppressing an immunological and/or inflammatory process, comprising administering to an individual in need of such treatment, an effective NO-synthase inhibiting amount of N,N-bis(2-pyridyl)methyl-N,N-bis (3,4,5-trimethoxybenzylethylenedinmine;

Group V, claim 8, drawn to a method, i.e., a regime or regimen, for treating a contact hypersensitivity and/or an immune response, comprising administering an effective NO-synthase inhibiting amount of N,N-bis(2-pyridyl)methyl-N,N-bis (3,4,5-rimethoxybenzylethylenedinmine;

Group VI, claims 9, 10, 12 and 13, directed to a method, i.e., a regime or regimen, for treating a skin reaction neurogenic in origin, **or** for treating "sensitive skin", **or** for treating erythema, **or** for treating localized or diffuse erythemal skin rash, comprising administering an effective NO-synthase inhibiting amount of N,N-bis(2-pyridyl)methyl-N,N-bis (3,4,5-rimethoxybenzylethylenedinmine;

Group VII, claim 11, directed to a method, i.e., a regime or regimen, for increasing the barrier effect or moisturization of the skin, comprising administering an effective NO-synthase inhibiting amount of N,N-bis(2-pyridyl)methyl-N,N-bis (3,4,5-rimethoxybenzylethylenedinmine;

Group VIII, claim 14, directed to a method, i.e., a regime or regimen, for treating rosacea comprising administering an effective NO-synthase inhibiting amount of N,N-bis(2-pyridyl)methyl-N,N-bis (3,4,5-rimethoxybenzylethylenedinmine;

Group IX, claim 15, directed to a method, i.e., a regime or regimen, for inhibiting melanogenesis induced by UV-A and/or UV-B radiation, comprising administering an effective NO-synthase inhibiting amount of N,N-bis(2-pyridyl)methyl-N,N-bis (3,4,5-rimethoxybenzylethylenedinmine;

Group X, claim 16, directed to a method, i.e., a regime or regimen, for controlling sweating, comprising administering an effective NO-synthase inhibiting amount of N,N-bis(2-pyridyl)methyl-N,N-bis (3,4,5-rimethoxybenzylethylenedinmine;

Group XI, claim 17, directed to a method, i.e., a regime or regimen, for inhibiting hair loss, comprising administering an effective NO-synthase inhibiting amount of N,N-bis(2-pyridyl)methyl-N,N-bis (3,4,5-rimethoxybenzylethylenedinmine;

Group XII, claims 20-23, directed to composition suited for various therapeutic methods comprising an effective amount of, *inter alia*, N,N-bis(2-pyridyl)methyl-N,N-bis (3,4,5-rimethoxybenzylethylenedinmine.

Linking Claims

Claims 1 and 18 and 19 link inventions I-XI. The restriction requirement between the linked inventions is subject to the nonallowance of these linking claims. Upon the allowance of

the linking claims, the restriction/lack of unity requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Independent/Distinct Nature of Inventions/Undue Burden on Examiner

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I-XI involve the treatment of diseases/conditions/disorders having different pathoetiological characteristics, therapeutic considerations and different conventional treatment options which support the Examiner's finding. The objective of the methods could be accomplished by the use of any number of a different population of active agents. For example, inhibiting cell differentiation (Group I) could be effectively accomplished through the administration of an agent such as 5-fluorouracil while the inhibition of hair loss could be accomplished by surgical means, i.e., hair transplantation from the rear or a persons scalp to the front or by medical means such as by the application of minoxidil. Therefore, the inventions of Groups I-XII Inventions are unrelated except for the fact that each is directed to a treatment method of a condition/disease/disorder. Inventions are

unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Further the inventions of Groups I-XI and the invention of group XII are different in that they are related by method of use and product for use in such methods. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a composition containing N,N-bis(2-pyridyl)methyl-N,N-bis (3,4,5-rimethoxybenzylethylenedinmine, because it functions as a NO synthase inhibiting compound could be used to practice an invention that is does not have unity with any one of the inventions of Groups I-XII. An example of such would be the use of N,N-bis(2-pyridyl)methyl-N,N-bis (3,4,5-rimethoxybenzylethylenedinmine for the protection of the body against oxidative stress (see the present specification at page 4, paragraph [0021].

Further Election of Species

Should applicant elect either of Group XII, then *further election of a physiologically acceptable medium (claim 21) and of "at least one other active agent" (claim 23)* is required.

Should Applicant elect Group 1 above, *Applicant is further required, in reply to this action, to elect a single disease/condition species to which the claims shall be restricted if no generic claim is finally held to be allowable.* The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an

election. Also, upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above, i.e., in claims 21 and 23, do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the listing of different dosage forms and active agents involve different formulation and therapeutic considerations.

Applicant is advised that the reply to this requirement to be complete **must include** an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

November 9, 2005